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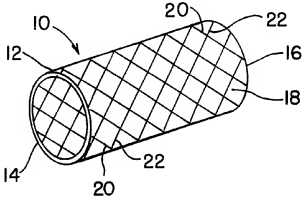
(54) Title: RESECTABLE SELF-EXPANDING STENT



(57) Abstract

A stent (10) for transluminal implantation comprising a single-piece tubular member (12) having a fenestrated sidewall (18) exhibiting a pattern of uniformly spaced openings defined by intersecting strands (20, 22) where the strands (20, 22) are integrally joined together at their points of intersection whereby the tubular member (12) can be radially compressed from a larger diameter to a smaller diameter by the application of a uniform inwardly directed radial force and which self-expands to a larger diameter when the radial compressive force is removed. The compression and subsequent self-expansion occurs without an appreciable change in the stent's length. By forming the stent (10) from a thermoplastic material, it may later be resected by carving it up into small pieces preferably using an electrosurgical instrument.

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RESECTABLE SELF-EXPANDING STENT

Background of the Invention

This invention relates generally to stent devices of the type intended to be inserted in tubular body organs for maintaining the organ in a patent condition, and more particularly to the design of a tubular stent whose thermoplastic material and geometry allow it to expand by itself from a radially compressed condition to a larger diameter and which can later be resected using an electrosurgical instrument.

Various forms of surgical stents are known in the art for maintaining a tubular body organ, such as a vein, artery, bile duct, fallopian tube or urethra, in a patent condition whereby body fluids can continue to flow in a normal fashion. Consider the condition termed benign prostatic hypertrophy where, in the male urinary system, with age, the prostate gland may swell. If the urethra which the gland surrounds is collapsed to the point where the flow or urine from the bladder becomes partially or even fully blocked, surgical intervention is often required. In surgically addressing this problem, a transurethral resection of the prostate is often performed in which portions of the prostate gland are shaved or resected away using an electrosurgical instrument called a resectoscope.

Another approach in treating an enlarged prostate involves inserting a dilatation catheter into the urethra and advancing that catheter until the balloon portion thereof is aligned with the prostate. Then the balloon is inflated to stretch and enlarge the urethra. Another treatment involves the insertion of a stent which functions to re-enforce the urethra at the site so that the tissue involved does not collapse to obstruct urine flow.

Where a stent is to be implanted transurethrally, it is an important characteristic that it possess a low cross-sectional profile to facilitate its being routed to the desired site within the urethra. Once appropriately positioned, it is desirable that the stent expand to a larger diameter and that it remain stable at that diameter over an extended period to provide the necessary support for inhibiting the urethra from again collapsing. Various devices having this property are described in the patent art. For example, in U.S. Patent No. 4,655,771 to Wallsten, there is described a tubular stent formed from braided metal wire which, when stretched longitudinally, will assume a relatively small diameter, but when it is allowed to spring back to a shorter length, an attendant increase in the diameter takes place. This device suffers from a number of practical

problems, not the least of which is the difficulty in properly positioning the stent so that, when released, it will collapse longitudinally and increase in size radially to the point where patency is established along the length of the prostate without having a portion of the stent protrude into the external sphincter so as to result in urinary incontinence or, alternatively, into the bladder where it would serve as a nidus for stone formation.

Also, if a stent of the type described in the Wallsten patent remains in the body for a period of several months, tissue ingrowth occurs and the stent, because of its open construction, becomes incorporated into the vessel wall where it is shielded from the urine. However, should it become necessary to explant the stent for any reason, it becomes extremely difficult to remove it through the urethra.

The Rosenbluth Patent 4,893,623 describes a tubular stent where the wall of the tube is slit in a predetermined fashion. To implant the stent, it is mounted over a deflated balloon on a dilatation catheter and then routed to the appropriate site in the tubular organ where the stent is to be deployed. The stent is made from a malleable metal so that, when the balloon is inflated, it will stretch the walls of the stent, creating an open lattice pattern. When the balloon is again deflated, the stent will remain stretched to the diameter established by the inflated balloon and the dilatation catheter can again be withdrawn from the body.

The stent arrangement described in the Rosenbluth patent also becomes difficult to remove once tissue ingrowth has occurred. Moreover, it is not self-expanding but, instead, must be stretched to a desired diameter through the application of an outward radial force. When that outside force is removed, the stent does not provide a residual outward radial force against the vessel wall. This may lead to undesired migration of the stent within the hollow vessel subsequent to its implantation and prior to the establishment of tissue ingrowth.

It is accordingly a principal object of the present invention to provide an improved tubular stent for use in the lumen of a tubular body organ.

Another object of the invention is to provide a tubular stent which may readily be resected from a tubular body organ at a later time if deemed necessary.

Yet another object of the invention is to provide a self-expanding tubular stent which is capable of being inserted through the lumen of a tubular body organ while exhibiting a small diameter, but which is self-expanding upon being released from its

insertion tool and which continues to exert a residual outward radial force against the vessel wall to maintain the stent in place.

A further object of the invention is to provide a tubular stent fabricated from a thermoplastic material, which is self-expanding and which is capable of being resected by being cut into pieces with an electrosurgical instrument.

Summary of the Invention

The foregoing features, objects and advantages of the invention are achieved by providing a stent for insertion into the lumen of a tubular body organ for maintaining that lumen in a patent condition where the stent consists of a tubular member having a fenestrated side wall allowing the member to be radially compressed from a larger diameter to a smaller diameter without undergoing any appreciable elongation and which can then expand when the radial compressive force is removed. It is preferably fabricated from a thermoplastic material, allowing same to be shaved or resected into smaller pieces for later removal should that become necessary. By controlling the electrical conductivity of the thermoplastic material so that it approximates that of human tissue, the ability to resect the stent using an electrosurgical instrument is enhanced.

The stent of the present invention comprises a non-braided thermoplastic web or mesh formed into a closed tube where the web or mesh includes a pattern of apertures of a predetermined shape that allows the closed tube to be radially compressed from a relatively larger diameter to a significantly smaller diameter when subjected to inward radially directed compressive forces uniformly applied over its surface, but which returns to a predetermined intermediate diameter when those compressive forces are removed. The intermediate diameter is sufficiently large to assure continuing outward force against the lumen wall. This tends to prevent unwanted migration prior to the time that tissue ingrowth occurs. A particularly efficacious device has been found to result as to have a pattern of openings defined by thin strands of the DELRIN® plastic whose radial thickness is about 1-1/4 - 2-1/4 times their circumferential width. With this pattern, the fenestrated tube may be radially compressed from a larger diameter, d_1, to a smaller diameter, $d_2 = d_1/4$. The ability of the stent to spring back to a predetermined outer diameter depends upon the degree of plastic deformation that the material incurs as well as the amount of creep encountered.

The features and advantages as well as the method of making and using the tubular stent of the present invention will become apparent to those skilled in the art from the following detailed description of a preferred embodiment, especially when considered in conjunction with the accompanying drawings in which numerals in the several views refer to corresponding parts.

Brief Description of the Drawings

Fig. 1 is a greatly enlarged perspective view of a self-expanding tubular stent in accordance with the present invention;

Fig. 2 is a side elevation view of the stent of Figure 1 at the time of manufacture and prior to being loaded into the stent delivery device;

Fig. 3 is a side elevation view of the stent of Figure 1 when radially compressed for insertion into the lumen of a tubular body organ;

Fig. 4 is a side elevation view of the stent of Figure 1 following release from its insertion tool; and Fig. 5 is a side elevation view of a stent having a pattern of apertures whose shape enhances the self-expanding characteristics of the device.

Detailed Description of the Invention

With reference to Figure 1, the self-expanding intraluminal prosthesis or stent is identified generally by numeral 10 and is seen to include a generally tubular member 12 having a pair of opposed ends 14 and 16 and a fenestrated wall surface 18. The stent of Figure 1 may be formed in a molding operation or, alternatively, may be created from a solid tube by laser or water-jet cutting the pattern of apertures so as to leave intersecting thread-like strips as at 20 and 22 therebetween.

The material from which the stent 10 is formed is preferably a thermoplastic having a high modulus of elasticity such that when it is subjected to inwardly directed radial forces uniformly applied over its surface, it will collapse to a lesser diameter but then spring back when the radial compressive forces are removed. A variety of medical-grade plastics are available which exhibit a high modulus of elasticity and which may be employed in fabricating the self-expanding stents of the present invention. For example, nylon or a suitable polyester may be used, but DELRIN® plastic, available through the Du Pont Corporation, has been found to be quite suitable.

Various manufacturing methods are available for fabricating the stent in accordance with this invention. Prototypes have been produced by appropriately mounting a solid tube of DELRIN® plastic on a mandrel and then, using a laser, the

fenestrations or apertures are cut through the thickness dimension of the wall to form a plurality of intersecting strands creating contiguous rhombic apertures. The intersecting strands are integrally joined at their points of intersection. With no particular limitation intended, each of the individual strands 20, 22 may be 0.015 in. thick in the radial direction and 0.010 in. wide in the circumferential direction. The laser may be computer-controlled insuring accurate spacing and precise line definition.

In a production setting, it is contemplated that the stents of the present invention may be formed in a molding operation which results in very low-cost production in comparison to the laser cutting method.

Referring next to Figures 2 through 4, at the time of manufacture, the diameter of the stent 10 is purposely oversized compared to the size of the lumen in which it is intended ultimately to be implanted. For example, it may be designed to initially have an outside diameter, d_1, as shown in Figure 2. Prior to insertion into the lumen of the hollow body organ to be supported, the stent of Figure 2 is radially compressed into an insertion tool and will collapse as shown in Figure 3 to exhibit a significantly lower diameter, d_2. When the tool and stent have been routed through the body lumen to the location where the stent is to be placed, it is released from the tool and allowed to expand to a diameter, d_3, which is less than diameter, d_1, (due to plastic deformation) and thereby provides support to the walls of the tubular organ which, in Figure 4, is identified by numeral 24.

While collapsing the stent to its smallest diameter, d_2, (Figure 3) results in some measure of plastic deformation, by originally over-sizing the stent as shown in Figure 2, it is capable of self-expansion to a working diameter, d_3, as shown in Figure 4. In fact, the stent is preferably designed such that when in position within the body organ, it will continue to exert a slight outward force against the internal walls of the body organ, thus tending to maintain the stent in position and reducing the tendency of the stent to migrate. Alternatively, appropriately disposed, radially-projecting finger-like barbs may be incorporated to resist such migration.

By loading the stent of Figure 2 into its insertion tool and thereby reducing its size to that shown in Figure 3, immediately prior to the implantation thereof, creep deformation, which is time dependent, is minimized.

In the stent shown in Figure 1, the openings are shaped like a rhombus. Good results have been achieved when the acute angles thereof are in the range of from 40°

to 60° such that the corresponding obtuse angles fall into the range of from 140° to 120°. Computer analysis has shown that this shape results in a concentration of stress forces at the points of intersection of the strands where they are integrally joined. By shaping the openings as shown in the stent of Figure 5, the stress concentration points are significantly reduced. The apertures or openings in Figure 5 may be described as those which result when the strands defining those openings have a sinusoidal pattern and where the negative peaks of a first strand integrally join to the positive peak of an adjacent strand. Because the apertures resemble the eye opening of a human, for ease of description, they are referred to herein as eye-shaped apertures. Because the intersecting strands are integrally joined at their points of intersection, the opposed ends of the stent are free of sharp points which occur when a braided tube structure of the type disclosed in the Wallsten patent is cut to a desired length. Hence, the stent of the present invention is less traumatic to tissue at the time of its implantation.

By forming the stent of the present invention from a suitable thermoplastic material and by introducing an additive to the material, its electrical conductivity can be made comparable to that of the tissue in which the stent will become embedded. Should it become necessary or desirable to later remove the stent device, an appropriate electrosurgical instrument may be used to cut through both the involved tissue and the stent material so that the pieces resulting can be withdrawn through the body lumen in which the stent had been positioned. The fact that the conductivity of the tissue and the stent material are approximately the same results in greater uniformity and control of the electrosurgical current as the resection takes place.

CLAIMS

1) A stent (10) for insertion into a tubular organ for maintaining the organ patent, comprising a single-piece tubular member (12) having a fenestrated side wall (18) exhibiting a pattern of spaced openings defined by intersecting strands (20, 22), the strands (20, 22) being integrally joined together at their points of intersection to allow said tubular member (12) to be radially compressed from a larger diameter to a smaller diameter and which self-expands when the radial compressive force is removed.

2) The stent (10) as in Claim 1 wherein said tubular member (12) is formed from an electrically resectable material.

3) The stent (10) as in Claim 2 wherein said electrically resectable material is a thermoplastic.

4) The stent (10) as in Claim 3 wherein said resectable material is DELRIN® plastic.

5) The stent (10) as in Claim 2 wherein said electrically resectable material has an electrical conductivity approximately that of body tissue.

6) The stent (10) as in Claim 1 wherein said openings are generally parallelogram shaped.

7) The stent (10) as in Claim 1 wherein said openings are generally eye-shaped.

8) The stent (10) as in Claim 1 wherein said strands (20, 22) have a radial thickness in the range of from 1-1/4 to 2-1/4 times their width.

9) The stent (10) as in Claim 1 wherein the radially compression and self-expansion is unaccompanied by any significant change in length.

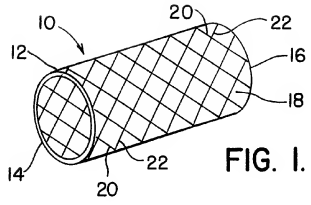


FIG. 1.

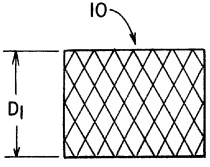
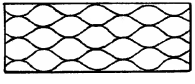


FIG. 2.

FIG. 5.



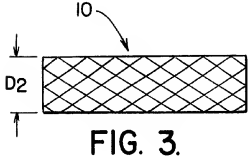
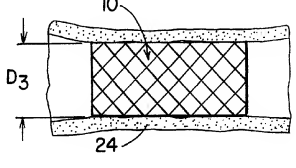


FIG. 3.

FIG. 4.



INTERNATIONAL SEARCH REPORT

International Application No PCT/US 91/08587

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61F2/06

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61F ; A61B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document, [11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
Y	EP,A,0 382 014 (ADVANCED CARDIOVASC. SYSTEMS INC.) 16 August 1990 see column 4, line 53 - column 5, line 2; claim 2; figure 5 ---	1,6,7,9
Y	FR,A,1 602 513 (NATIONAL R&D CORP.) 21 December 1970 see page 2, last paragraph; figure 4 ---	1,6,7,9
A	US,A,4 944 746 (IWATA ET AL.) 31 July 1990 see claim 1 ---	2-5
A	US,A,4 820 298 (LEVEEN ET AL.) 11 April 1989 see claims 1,3 ---	3

° Special categories of cited documents :[10]

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"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
16 MARCH 1992	24.03.92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	VILLENEUVE J.M.

Form PCT/ISA/210 (second sheet) (January 1985)

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. US 9108587 SA 54645

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 16/03/92

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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FR-A-1602513	21-12-70	None	
US-A-4944746	31-07-90	JP-A- 2084964	26-03-90
US-A-4820298	11-04-89	None	